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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,936	09/22/2003	John Moberg	1001.1715101	1606

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EXAMINER	
LALLI, MELISSA LYNN	

ART UNIT	PAPER NUMBER
3728	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,936	MOBERG, JOHN	
	Examiner	Art Unit	
	MELISSA L. LALLI	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-13,19-21 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-13,19-21 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment submitted on June 1, 2009 has been acknowledged. Amended claims 1, 19, and 26 have been entered. Therefore, claims 1-4, 7-13, 19-21, and 24-26 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 1 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Roll.

Regarding claim 1, Roll discloses an elongate medical device (fig. 2) suitable for packaging in a tubular member (106) having a lumen defined by an inner surface, the elongate medical device comprising: an elongate shaft (113) extending from a proximal portion of the elongated medical device to a distal portion of the elongated medical device; a hub assembly (104) connected to the elongate shaft such that the elongate shaft extends distally from the hub assembly, the hub assembly including a portion manufactured from a first material; and an interference fit member (105) including a second material (abstract, line 19) and disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the interference fit member (IFM) are disposed within the lumen of the tubular member (fig. 3).

Regarding claims 7-13, Roll discloses the second material (rubber) being more compressible than and readily deformable compared to the first material (fig. 2).

Rubber is an elastomeric material and the IFM is disclosed as being an O-ring (col. 3, lines 6-10). Silicone is a form of rubber. The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Claim Rejections - 35 USC § 103

4. Claims 1-4, 7-11, 13, 19-21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch et al. (McGlinch) in view of Gadberry et al. (Gadberry).

Regarding claim 1, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22) extending from a proximal portion of the elongated medical device to a distal portion of the elongated medical device; a hub assembly (30) connected to the elongate shaft such that the elongate shaft extends distally from the hub assembly, the hub assembly including a portion manufactured from a first material (col. 3, lines 13-18); and an IFM (40) disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) including a second material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material

of Gadberry for the IFM (40) of McGlinch in order to create a frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

Regarding claim 2, McGlinch discloses the hub assembly (30) having a distal portion including a segment with a generally circular cross section including a first material (fig. 1). Gadberry discloses the IFM (65) being disposed about a channel (64) extending circumferentially around the tubular member (23). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the channel (64) of Gadberry on the circular segment of the distal portion of the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal when the elongate medical device is enclosed as taught by Gadberry.

Regarding claim 19, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22) having a proximal portion and a distal portion; a hub assembly (30) connected to the proximal portion of the elongate shaft such that the elongate shaft extends distally from the hub assembly, the hub assembly including a portion manufactured from a first material (col. 3, lines 13-18); and a circumferential IFM (40) configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the hub assembly including a circumferential channel and the IFM being disposed about a portion of the

circumferential channel and comprising an elastomeric material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with a circumferential IFM (65) disposed about a circumferential channel (64) and comprising an elastomeric material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and elastomeric IFM (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal when the elongate medical device is enclosed as taught by Gadberry.

Regarding claims 3, 4, 20, and 21, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the IFM is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

Regarding claims 7-11, and 13, 24 and 25, Gadberry discloses the second material being more compressible than and readily deformable compared to the first material (figs. 3 and 6). The second material is considered elastomeric and the IFM is disclosed as an O-ring (col. 4, lines 25-27). The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Regarding claim 26, McGlinch discloses an elongate medical device packaging assembly (fig. 1) comprising: a tubular member (10) having a proximal end, a distal end, and a lumen (14) defined by an inner surface; a hub assembly (30) including a proximal

end and a distal end, the hub assembly including a portion manufactured from a first material (col. 3, lines 13-18); an elongate shaft (22) having a proximal end and a distal end, the proximal end of the elongate shaft being connected to the hub assembly such that the elongate shaft extends distally from the distal end of the hub assembly; an IFM (40) disposed about a portion of the hub assembly; and wherein the elongate shaft and at least a distal portion of the hub assembly are disposed in the lumen of the generally tubular packaging member such that the interference IFM is engaged with the inner surface of the tubular member to form an interference fit with the inner surface of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device packaging assembly (10) having a tubular member (23) with an IFM (65) including a second material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create a frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch and Gadberry as applied to claims 1 and 11 above, and further in view of Roll.

Regarding claim 12, McGlinch and Gadberry do not disclose the O-ring (65) comprising silicone; however, Roll discloses a similar elongate medical device (fig. 2) suitable for packaging in a tubular member (106) with an O-ring (105) formed of rubber (abstract, line 19). Silicone is a form of rubber. It would have been obvious to one

having ordinary skill in the art at the time of the invention to have used silicone to form the O-ring used in the elongate medical device of McGlinch and Gadberry as it is well known in the art. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

6. Applicant's arguments, filed October 29, 2008, have been fully considered but they are not persuasive.

Regarding applicant's arguments of the 102(b) rejection of claims 1 and 7-13 by Roll, the examiner respectfully disagrees. As can be seen in fig. 2 of Roll, the elongate shaft (113) extends from a proximal portion of the elongated medical device to a distal portion of the elongated medical device and the hub assembly (104) is connected to the elongate shaft such that the elongate shaft extends distally from the hub assembly. Contrary to applicant's assertion of the location of the distal and proximal portions, the proximal and distal portions may be interpreted at varying locations depending on how the medical device is positioned; hence, Roll anticipates all of the claim limitations as discussed in the rejection above.

Regarding applicant's arguments of the 103(a) rejection over McGlinch and Gadberry, the examiner respectfully disagrees. The rationale for substituting the O-ring/IFM (65) made of an elastomeric material of Gadberry for the IFM of applicant is discussed in detail in the rejection of claims 1, 19, and 26 above. The O-ring (65) of Gadberry is similar to the IFM of the present application in a sense that both form a seal

between two elements. The "interference fit" as applicant affirms is created by the IFM is equivalent to a seal. There is no structural or functional difference between the interaction of an O-ring and a tubular member and applicant's IFM and a tubular member. In both situations, a seal is created between the tubular member, the O-ring/IFM, and the hub assembly. Also, it is inherent that the O-ring of Gadberry forms a friction fit between the hub assembly and the tubular member whether or not such is explicitly stated. Gadberry may disclose alternate structures to maintain attachment of the cap and the tube; however, such is considered an additional locking means between the two parts which does not take away from the seal created by the O-ring. It is a matter of obvious design choice to include additional structures such as detents or screw threads to provide additional support for attachment of the two structures. The O-ring could certainly function to maintain the attachment between the cap (27) and the housing (25) without the use of a detent or screw threads. Additionally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA L. LALLI whose telephone number is (571)270-5056. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLL
7/13/09

/Mickey Yu/
Supervisory Patent Examiner, Art Unit 3728